

Specifications for Creating PDF Version of Study Reports revision 1

Format of Original Source Document		
Feature	Specification	Comments
Software	Any word processing or desktop publishing software for IBM type or Macintosh type computer.	Use any software that can print output to a postscript printer format file (.ps) and subsequently converted to PDF format (.pdf). One purpose of using Adobe® Acrobat® is to not restrict original label creation to specific software.
Page size	8.5" × 11".	An A-4 source document is allowable provided the resulting PDF page size is set for 8.5" × 11".
Margins	At least 1" on all sides.	
▲ Font Size/Style – Text of study report.	12 point Times New Roman	<p>12 point is desired, but if the PDF is created from an A-4 size source, make it fit 8.5 × 11 format. It's OK if resulting font size is not 12 point.</p> <p>Use of specialty fonts for math or scientific purposes is allowable provided these fonts are embedded in the resulting pdf file.</p>
Font Size/Style – Tabular information	12 point Courier.	Courier is preferred for tabular data since it is a fixed width font. Other fixed width fonts may be suitable provided they are embedded in the resulting pdf file.
Font Type	Microsoft® True Type® or Adobe® Type 1.	Do NOT use proprietary fonts. These can not be embedded in PDFs. Acrobat will try to use a substitute font but this may alter document format, appearance, and print.


Feature	Specification	Comments
Tables	Use software “table” function rather than tabs or blank spaces to create tabular layout.	Tabular text initially created in true tables and then converted to PDF readily exports to other software. Use of tabs to create the look of a table does not result in readily exportable data.
Subscripts & Superscripts	In tables, use letters; not numerals.	Tables may be converted to other software during review process. Numerals may be converted to full size which may result in mis-leading numbers in tables. Therefore, use letters.
Text Color	Black.	
▲ Indicates that there has been some change in the guidance from the previously posted version.		

Format and Creation of PDF File		
Feature	Specification	Comments
Printing	Create PDF document after paper version passes 86-5.	See guidance re <i>Preparation and In-Processing of Studies Submitted in PDF</i> . Production sequence – paper, then PDF – may change depending on registrant experience assembling full submissions.

Feature	Specification	Comments
▲ File Format	Adobe® Portable Document Format (PDF) – Version 1.4 or higher.	
▲ PDF File Compatibility	Adobe® Acrobat® 5.0 or higher.	EPA staff will use Adobe® Acrobat® 5 (full program) to perform reviews.
▲ Software	Use any software that can create a PDF version 1.4 or higher and which can control the required settings specified in this and other guidance documents.	
Conversion to PDF Options.	Goal is to create a text PDF rather than an image PDF. This allows text to be interpreted as words rather than images thus allowing indexing, searching, text comparison, etc.	
• First choice	Convert directly from electronic source document.	This provides full indexing for text and tables.
• Second choice	<p>Scan paper copy of study report. Process through optical character recognition (OCR) software such as Adobe Acrobat Capture, ABBYY® Fine Reader®, or ScanSoft® OmniPage® Pro to create text PDF providing text extraction and indexing capabilities.</p> <p>Refer to scanning requirements below.</p>	<p>Data submitter does not have to quality assure the underlying OCR., however, more accurate text recognition in the submitted PDF file will allow for increased utility by OPP reviewers.</p> <p>Avoid overuse of cell splits and joins in tables to avoid conversion problems.</p> <p>Do not use shading in tables as it may not convert accurately.</p>
• Third choice	<p>Scan without OCR.</p> <p><i>This option should only be used for photographs, chromatograms, and any other graphic-based data where use of OCR is impractical.</i></p>	This option produces a graphic-only PDF file and does not allow for required text manipulation.

Feature	Specification	Comments
▲ Scan Text and tables	Black and white 300 dpi minimum.	The greater the scanning resolution, the more accurate will be any OCR process.
▲ Scan handwriting	Black and white 300 dpi minimum.	
▲ Scan Color Photos	100 - 600 dpi, 24-bit RGB depending on nature and purpose of photos. If high resolution is critical, use 600 dpi but attach as supplemental file.	To avoid the creation of very large files and the need for users to scroll large photos, scan at the minimum resolution needed to achieve an accurate rendition of the original. If significant detail is required then use higher resolution.
▲ Scan Black and White Photos	100 - 600 dpi, 8-bit gray scale. If high resolution is critical, use 600 dpi but attach as supplemental file.	See note for color photos above.
Scan Gels and Karyotypes	100 - 300 dpi, 8-bit gray scale. Do not use photographs.	
Scan Plotter Output	Capture digitally or scan at 300 dpi.	
Scan Chromatography	300 dpi.	
▲ Adobe Acrobat Distiller Job Options	Use Agency supplied downloadable job options file or manually configure job options using Software Settings for the Creation of PDF Files for Electronic Study Submission guidance available on this web site.	This requirement applies to use of Adobe Acrobat Distiller in the creation of the study report .pdf file.

Feature	Specification	Comments
Security	Do not lock file in any way. Specifically select the following settings: Permissions: <ul style="list-style-type: none"> • Allow content copying and extraction • Comment authoring, form field fill-in or signing. Printing: <ul style="list-style-type: none"> • Fully allowed. 	Goal is to allow reuse of PDF information and printing. Note: Security options may change in the future.
File Size	No limit.	PDF has no limit on file size. But the PC on which someone builds or reads the files can introduce constraints.
▲ Folder and File Naming Convention – Study reports	<pre>../Guideline number/MRID/MRID_descriptive_name.pdf</pre> <p>where MRID_descriptive_name is the MRID assigned to the study followed by a short description. ie “45612301 Rat acute tox.pdf”</p>	<p>The full path name must be less than 200 characters in length including all folders, subfolders, and file name.</p> <p>For assorted product chemistry in one study report, use the general series number for guideline number. ie “63” for assorted physical/chemical characteristics.</p> <p>For non-guideline studies, use folder named “non-guideline studies”.</p> <p>All text, figures, and tables related to each study should be in a single file. If supplemental files are submitted, they may be in a separate file.</p>
▲ Folder and File Naming Convention – Supplemental Files/Review Aids	<pre>../Guideline number/MRID/MRID_descriptive_name.xxx</pre> <p>unless specific guidance exists for the specific supplemental data type where .xxx is the appropriate extension for the file type.</p>	<p>Refer to supplemental/review aids guidance for specific information on naming of supplemental files and review aids.</p> <p>Include all supplemental files in the same folder as the parent study report. See file naming requirements above.</p>

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Page Size	8.5" × 11".	
Margins	At least 1" on all sides.	
Page Orientation	Use source document orientation.	
Page Numbering	Same as source document.	
 Font Embedding	Embed all fonts except for Base 14 fonts.	<p>Goal is to embed all fonts used in document to ensure correct formatting, appearance, and printing of document. It is recommended that the PDF be created on the same computer on which the original source document was created so the same non-proprietary fonts are available. Using the “when embedding fails - cancel job” option will make it obvious when font problems exist.</p> <p>Do NOT use proprietary fonts. These can not be embedded in PDFs. Acrobat will try to use a substitute font but this may alter document format, appearance, and print.</p>
Electronic Signatures	Not implemented at present.	Electronic submissions must include <i>Certification with Respect to Data Integrity</i> pending development of Agency policy and standards on electronic signature
Bookmarks – Submission Transmittal letter	Create bookmark for each item listed in the transmittal letter.	This can include all elements of an application (Application form, label, studies, etc.)
Bookmarks – Study table of Contents	Create bookmark for each item in table of contents of study report document.	Follow OPP guidance for required bookmarks for specific study types.
Bookmark Hierarchy	Limit to no more than four levels in either full submission or within a single study.	Consensus is that people get ‘lost’ when there are more than four levels.

Feature	Specification	Comments
Hypertext Linking	Yes. Use <i>Inherit Zoom</i> magnification setting.	
Link Supporting Information	Yes, when not on the same page. Link tables and appendices to references in text.	
Link Style	Blue text.	If printed, paper version is being used, the blue won't appear. Underlining (in addition to blue text) takes many steps. Since linking should be obvious from the context in which it appears, no special markings need be done for paper version.
▲ Indexing	Not required at this time.	This includes both the Document Property > Summary Data of the PDF and Indexing using the Adobe® Acrobat® Cataloging capability.
Open Dialog Box	Use <i>Bookmarks & Page</i> . If no bookmarks, then <i>Page only</i> .	
Electronic Supplemental Files/Review Aids	See Supplemental Files/Review Aids guidance documents.	
▲ Chemical Structure Information	Submit as Rdf files, Sd files, or Mol files.	Submit mechanistic and metabolic pathway data when either a new chemical submission or additional data on existing chemicals. Use any software capable of creating the appropriate file type. OPP is using MDL® ISIS software for review purposes. Attach file(s) to study PDF and bookmark /link accordingly.
▲ <i>Indicates that there has been some change in the guidance from the previously posted version.</i>		

Submission of PDF Study		
Feature	Specification	Comments
Submission Medium	Compact Disk (CD-ROM).	Disk must be compatible with Windows 95 or higher. Do not use floppy disks.
▲ Labeling of CD and Jewel Case	Registrant, Active Ingredient, brief description of application on both.	Provide only one submission per CD, however, multiple CDs may be used for one submission if required.
▲ Transmittal Document	Locate the transmittal document PDF file in the root folder of the of the CD-ROM. Name this file "TRANSMITTAL.PDF".	
How to Submit	See guidance document <i>Preparation and In-processing of Studies Submitted in PDF</i> .	
Where to Submit	Send via courier service to OPP physical location: Document Processing Desk (E-SUB) U.S. EPA - Office of Pesticide Programs Room 266A 1921 Jefferson Davis Hwy. Arlington, VA 22202	Do NOT send via US mail. The irradiation procedures currently used on Washington, DC mail will damage the CD-ROM..
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